REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1 to 16 are under active examination.

Support for Amendments

New independent claim 16 has been added. This is based on a combination of currently pending claims 1 and 6. It therefore differs from claim 1 only in that the proteomics analysis entails the two specific steps recited in claim 6.

Claim Rejections under 35 USC 112

2. Claims 1 to 8 are rejected under 35 USC 112, first paragraph, because the Examiner believes that the specification does not provide reasonable enablement for any biological profiling technique other than a proteomics analysis involving a comparative analysis of the proteins of target cells with and without the effect of the medicinal plant material.

   In reply, it is submitted that there is indeed enablement for biological profiling techniques other than a proteomics analysis as mentioned above. This is because biological profiling techniques are themselves known and thus capable of being performed by any person of routine skill in the relevant art. In the present invention as defined in claim 1 the applicant is not laying claim to biological profiling techniques in isolation. Rather, the applicant is exploiting such techniques which, although known and well-established in and of themselves, are part of an overall analytical package which is novel and inventive over the prior art.

It can therefore be seen that the person of skill in the art would have no difficulty in carrying out the presently claimed process because, as far as the biological profiling techniques are concerned, he or she would merely be conducting well-established procedures. Examples of these include the receptor binding assays and enzyme inhibition assays mentioned in the specification on page 14, lines 3 to 9. That passage makes it quite clear that conventional assay protocols are to be used.

As far as the proteomics analysis is concerned, similar comments apply. Thus, while the steps identified by the Examiner represent a typical way of carrying out a proteomics analysis, alternative methodologies are not excluded. The person of skill in the art would be well aware of these and would recognise that they could be deployed in the process of present claim 1 without any detriment whatsoever to the success of the technique. Such methodologies are part of a skilled person's routine skill and knowledge and do not need to be explicitly recited in the specification. The specification is accordingly fully enabled as it stands with regard to all types of biological profiling techniques and all manner of proteomics analyses.

Applicants have added new independent claim 16, in which the proteomics analysis is limited to the specific process steps recited in currently pending claim 6. In all other respects claim 16 is identical to claim 1.

3. Claims 1 and 9 have been rejected under 35 USC 112, second paragraph on the alleged basis that the reference to "preparing a test extract" in each claim contradicts the subsequent requirement that the NMR data should reflect "the totality of the compounds in the plant material". It is pointed out in reply that, by definition, it is impossible to obtain an NMR spectrum of total plant material.

Thus, as is well-known to those of skill in the art, it is necessary for the material to go into solution before an NMR spectrum can be obtained. However, the formation of a solvent-derived extract unavoidably entails a degree of selectivity since no solvent system is capable of solvating every single phytochemical present in a plant material.

With this in mind, the person of skill in the art will readily appreciate that the solvent chosen for the process of the invention must have a broad solvating power so that representatives of as many different classes of compound as possible are dissolved and therefore able to contribute to the resulting NMR spectrum. The person of skill in the art would accordingly also appreciate that conducting the process "such that the NMR data reflect the totality of the compounds in the plant material which respond to the NMR technique being used" required an appropriate selection of solvent. That selection would be within such a person's capability.

In response to the rejection of claim 2 for being unclear, because it does not specify that a proteomics is performed for the candidate sample, claim 2 has been amended so that step (ii') corresponds to step (ii) of claim 1. As a consequence claim 2 now requires the candidate sample to be submitted to both the NMR spectroscopy/computer-based pattern recognition technique and the one or more biological profiling techniques which include a proteomics analysis. This makes it clear that the selection of the candidate sample in step (iv') of claim 2 requires compliance on the basis of both the NMR/computer-based pattern recognition results and the biological profiling results.

The Examiner has rejected claim 3 under 35 USC 112, second paragraph, because it is allegedly unclear what the notion of compliance means in that claim. In reply, it is submitted that the person of skill in the art would have no difficulty

whatsoever in understanding the meaning of the term in the context of biological profiling techniques in general, particularly given the guidance in the specification. For instance, at page 13 lines 15 to 18 of the specification, there is a disclosure of accepting or rejecting candidate samples depending on whether they give the same overall pattern of change in protein expression. However, the skilled biologist would not be given to understand from this that the overall pattern had to be absolutely identical in order for compliance to be acknowledged. Rather, it would be abundantly clear that allowance should be made for experimental error and inherent natural variation. The person of skill in the art would therefore fully appreciate that "compliance" means that the results of the biological profiling should be broadly the same although not necessarily identical. There would be no difficulty for a skilled person in recognising the extent of the boundaries of acceptability in this context.

In response to the rejection of claim 7 under 35 USC 112, second paragraph, claim 7 has been cancelled.

Claims 1 to 8 have been rejected under 35 USC 112, second paragraph, because the Examiner alleges that it is unclear whether or not there is any correlation between the NMR data and the biological profiles of the standard and test samples. It is submitted in reply that this is again a point on which the person of skill in the art would apply his or her normal skill. That person would acknowledge the fundamental principle that a defined chemistry equates to a defined biology. In other words, if the profiles of two samples of plant material are identical in chemical terms, as revealed by NMR and computer-based pattern recognition, those samples must necessarily give identical biological responses. In practice, however, the present invention allows for a sphere of acceptability around the data

obtained from the NMR/computer-based pattern recognition analysis. This is discussed in the specification at, for instance, page 9 lines 8 to 12.

In defining "compliance" in relation to the analysis of the plant's chemistry, therefore, allowance is made in the present invention for intrinsic variation of a limited scope. It follows that there could in practice be differences between the biological responses of two samples which are judged to be "the same" in terms of NMR and computer-based pattern recognition because they are both within the sphere of acceptability on the principal component analysis (PCA) score plot.

These points would be well understood by a skilled addressee of the specification. In summary, therefore, the person of skill in the art would recognise that the very fact of allowing for a sphere of acceptability on the PCA score plot allows for minor variations in the biological responses of samples which are otherwise considered to be "in compliance" for the purposes of the present invention.

Claim rejections under USC 102

6. Claims 9 to 11 stand rejected under this heading as being anticipated by Vercauteren *et al* (WO 96/18911). With respect, applicant traverses this rejection. The technique disclosed in Vercauteren is based on an entirely different approach to plant characterisation from that employed in the present invention.

The objective of the process of present claim 9 is the provision of a standard specification for a medicinal plant material. This specification is one with which future candidate samples of that plant can be compared. The process comprises

NMR spectroscopy combined with a multivariate analysis of the resulting data, the process being conducted in such a way that the NMR data reflect the totality of the compounds in the plant material being tested which respond to the particular NMR technique being used. It is thus, by implication, an essential feature of the process that there is no prior isolation of selected components from the plant material. Rather, the process is carried out in such a way that every compound present in the plant extract, which is responsive to the NMR technique, will contribute to the data which are collected and then statistically evaluated by the multivariate analysis.

In contrast, the process of Vercauteren is intended to identify plant species (and hybrids or lower-order taxons thereof) in order to determine their origin. The technique is particularly applicable to wine identification and indeed the specific Examples in the specification relate solely to the analysis of grape extracts. There is no disclosure in Vercauteren of applying the technique to medicinal plants. Furthermore the process of Vercauteren exploits polyphenols, which are naturally present in grape material, as marker compounds. Polyphenol extracts of the plant material are prepared in Vercauteren and then subjected to NMR techniques which are optimised for polyphenols such as catechin and epicatechin. The approach is therefore entirely different from that enshrined in present claim 9, which does not rely on the isolation of specific marker compounds and the consequential optimisation of the NMR and pattern recognition system to measure and analyse only those compounds. Unlike the method of Vercauteren, the present process does not focus on a pre-determined fraction isolated from the crude plant material.

The above discussion shows that the process defined in present claim 9 is based on an entirely different approach to the analysis of plant material from that of Vercauteren, and furthermore is restricted to medicinal plants (of which no

mention is made in Vercauteren). The claimed process is thus novel over Vercauteren.

Since claim 9 is novel over Vercauteren, claims 10, 11 and 15 are also novel because they depend from claim 9 and therefore derive their patentability from it. In view of this, and the above comments, it is submitted that the rejection of claims 9 to 11 and 15 should be withdrawn.

Rejections under 35 USC 103

9. Claims 12 to 14 stand rejected under this heading for being obvious over Vercauteren, discussed above. The applicants submit in reply that claims 12 to 14 are all dependent, directly or indirectly, on claim 9. Claim 9, in turn, is not obvious over Vercauteren. The discussion above clearly shows that the process of claim 9 is based on an entirely different approach to the analysis of plant material from that taught by Vercauteren. The process claimed in claim 9 is therefore not only novel but also inventive over this cited document. Claims 12 to 14 are therefore also inventive by virtue of their dependency on claim 9. It is accordingly submitted that the rejection under this heading should be withdrawn.

Reconsideration and favorable action are solicited.

Respectfully submitted,

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